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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,950	08/11/2005	Christopher J. Speirs	SPEI3002	1941

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,950	SPEIRS ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/09 has been entered.

Response to Amendment

The amendment to the claims filed on 11/12/09 does not comply with the requirements of 37 CFR 1.121(c) because the claims are not numbered in ascending numerical order. The new claims must be numbered consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not) in compliance with 37 CFR 1.126. It is noted that claim 78 is immediately followed by claim 80, while claim 84 is followed by claim 74.

Election/Restrictions

This application contains claims directed to the following patentably distinct species:

1) polymethacrylate material is: a) a methacrylic acid copolymer, b) a copolymer of methacrylic acid and methyl methacrylate having ratio of about 1:2, or c) a copolymer of methacrylic acid and methyl methacrylate having ratio of about 1:1;

2) pH dissolution dependent coating material of the plurality of first particles and second particles are: a) the same, or b) different; and

3) active compounds in the plurality of first and second particles are: a) the same, or b) different.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 63 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing**

the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 63-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 is rejected in the use of the phrase "wherein the coating...is contiguous with the surface of the first [second] pellet". The phrase is vague because the term "contiguous" as defined by the Webster's Dictionary to have a number of meaning that includes: 1) sharing a boundary or edge, nearby, or immediately preceding or following in time. As such, the metes and bounds of the patent protection desired are unascertainable. Without the specific teaching in the present specification for the term contiguous, the examiner is allowed to apply the broadest reasonable interpretation. Thus, until further clarification, the term contiguous is read as nearby.

Claim Rejections - 35 USC § 102

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 63-75 and 79 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischer et al. US 6,267,990.

Fischer teaches a controlled release preparation comprising at least two populations of pellets: a first delayed release type of pellet; and a second delayed release type of pellet (abstract; claims). The ratio of the first and second delayed release type of pellet ranges from 1:2 to 1:7 (column 2, lines 10-14). The pellets of the first and second delayed release can be coated with the same materials, such as Eudragit or Aquacoat (column 2, lines 39-62).

Claims 63-82 and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinicke et al. US 5,834,024.

Heinicke teaches a controlled release formulation comprising short and long lag pellets of diltiazem (abstract). The diltiazem core is coated with polymer or mixture of polymers such as Eudragit S, Eudragit L, or Eudragit L 30D (column 5, lines 24-44). The thickness of the coating is increasing or decreasing to obtain the desired short and long lag pellets (column 4, lines 21-38). Example 1 shows the short lag pellet comprises about 12% weight gained of the coating polymer, and the long lag pellet comprises about 29% weight gained of the coating polymer. Heinicke further teaches the particle size of the pellet is about 1400 μm (example 1). The combined pellets are filled into capsule (column 6, line 64).

Claim Rejections - 35 USC § 103

Claims 63-82 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinicke et al. US 5,834,024, in view of Fischer et al. US 6,267,990.

Heinicke is relied upon for the reason stated above. Heinicke further does not teach the claimed ratio of the short and long lag pellets. However, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable coating weight gain, as well as the ratio between the short and long lags depends in the release profile desired. This is because Heinicke teaches a controlled release dosage form effective to permit release of active agent at different cites in the GI tract over a 24 hours period, and because Heinicke teaches a weight gain of about 29%, with a mixture of 40% short lag and 60% long lag pellets (example 1). To be more specific, Heinicke is cited in view of Fischer for the teaching of the ratio of the short and long lag pellets.

Fischer teaches a controlled release preparation comprising at least two populations of pellets: a first delayed release type of pellet; and a second delayed release type of pellet (abstract; claims). The ratio between the first and second delayed release pellets ranges from 1:2 to 1:7 (column 2, lines 10-14). The pellets of the first and second delayed release can be coated with the same materials, such as Eudragit or Aquacoat (column 2, lines 39-62). Thus, it would have been obvious to one of ordinary skill in the art to optimize the controlled release composition of Heinicke to include the pellets population having the claimed ratio, because it is known in the art.

Claims 63-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speirs US 5,834,021, in view of Andre et al. EP 1064938 A1.

Speirs teaches a controlled release dosage form comprising enterically coated pellet of prednisolone metasulphobenzoate incorporated into enterically coated capsule (abstract; and column 5, lines 61-67). Enteric coating polymer includes Eudragit S or Eudragit L (column 5, lines 9-34). The pellet has a diameter in the range of 700-1700 μm (column 4, lines 66-67). Spear further teaches that the thickness of the Eudragit coating on the pellets is between 15-30% based on the uncoated granule (column 5, lines 39-52).

Speirs does not expressly teach dosage form comprising plurality of particle with different release profiles.

Andre teaches a multiparticulate dosage form comprising active core, coating with film forming polymer such as Eudragit polymer (abstract; and paragraphs 0015-0017). Andre also teaches capsule comprising different population of coated multiparticulate dosage form with different release profiles (page 5, lines 38-43; and examples). Active agent includes prednisolone (paragraph 0024). Thus, it would have been obvious to one of ordinary skill in the art to modify the prednisolone dosage form of Speirs to prepare a dosage form with at least a timed pulse in view of the teachings of Andre. This is because Andre teaches that a timed pulse release dosage form allows targeting of a drug to a given site of the GI tract, in particular the colon (paragraph 0006), because Andre teaches a pulsed release dosage form that allows reduced dosing frequency, because Andre teaches a pulsed release dosage form suitable for

drugs including prednisolone, and because Speirs teaches the desirability to include a plurality of the coated pellets in a capsule for the delivery of prednisolone to the intestine (column 4, lines 38-43).

Response to Arguments

Applicant's arguments filed 11/12/09 have been fully considered but they are not persuasive.

Applicant argues that the phrases "wherein said coating material is applied directly onto the surface of the pellets" and "wherein the pH dissolution dependent coating material is contiguous with the surface of the first [second] pellet" are supported by the present disclosure. While the phrases are not explicitly recited, one skilled in the art would have understood that Applicants were in possession of this subject matter at the time of filing the application. For example, the present specification discloses coating pellets at page 10, lines 24-27; page 14, lines 12-19; page 15, line 27 to page 16, line 19 and Examples 1-9. The excerpts neither disclose nor suggest applying additional coating layers between the pellet and pH dissolution dependent coating material. There is also no discussion of applying the pH dissolution dependent coating material in a manner that would not result in the pH dissolution dependent coating material being contiguous with the surface of a pellet. As a result, one skilled in the art would have understood that the coating material of the present invention was applied directly onto the surface of the pellets and that the coating material was contiguous with the surface of the pellets.

The 112, 1st paragraph rejection has been withdrawn in view of applicant's Remarks.

Applicant argues that Fischer does not disclose a plurality of first and second particles having a coating of varying thickness. Applicant suggests that Fischer teaches that the coating for each pellet is of a uniform thickness.

However, a closer reading of the present specification, it is noted that the "varying thickness" referred to in the claims is directed to the various thickness of each group of pellets. The specification does not appear to provide support for the alleged limitation that the coating thickness of pellets in the same group has different thickness. See Examples 1-9 of the present invention. The examples disclose that the coating thickness ranges from 5%, 10%, 15%, 20% or 25% for each particular group respectively. See Example 4, which teaches a two particle populations such that group one particle has a coating weight gained of 15%, and the coating weight gained for the second particles is also of 15%. Accordingly, the teachings of Fischer read over the claimed limitations.

Applicant argues that the HEINICKE composition does not utilize a pH sensitive coating material as a film forming material in direct contact with a rough, irregular surface of a pellet. Indeed, there is no disclosure in HEINICKE of coating the surface of a plurality of first and second pellets directly with a pH sensitive material as a film

forming material for pH-mediated release of an active agent, as claimed (see independent claim 63).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a coating material that comes in direct contact with a rough, irregular surface of a pellet) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The present claims do not require the pellet surface to be rough and irregular. Further, as discussed above, under the 112, second paragraph rejection, absent specific teaching in the present specification for the term contiguous, the examiner is allowed to apply the broadest reasonable interpretation. As defined by Webster dictionary, contiguous can be translated to mean near by. Accordingly, "near by" permits coating that is near by but does not have to come in direct contact or immediate adjacent to the core. The same arguments are also applied to response to applicant's arguments with respect to Speirs.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615